> evidence of such intent with regard to nicotine in tobacco products. . . .
>
> Mr. Chairman, we now have cause to reconsider this historical view . . . This question arises today because of an accumulation of information in recent months and years. In my testimony today, I will describe some of the information.

Appendix 7 at 1-2 (footnote omitted). This testimony, like the reference to the *ASH* decision, adequately put the public on notice of FDA's past position.[1248]

Nor does FDA agree with the comment's argument that Congress, in reliance on past FDA pronouncements, enacted legislation precluding FDA from regulating tobacco products under the Act. As discussed in detail in sections IV. and V., above, the Agency has never categorically disclaimed jurisdiction over tobacco products and Congress has never expressly forbidden FDA from asserting jurisdiction over these products. The Agency had no affirmative obligation to posit in the Jurisdictional Analysis arguments it believes are legally infirm. *Cf. Florida Power and Light Co. v. United States*, 846 F.2d 765, 771 (D.C. Cir. 1988), *cert. denied*, 490 U.S. 1045 (1989).

Two tobacco industry comments also claimed that the Agency unfairly underplayed the complexity of issues such as "intended use," product categorization,

---

[1248] The Agency's decision not to include a prolonged discussion of past Agency decisions is also based on the fact that the Agency is operating under a different set of facts. *See* section IV., above. The Agency did not commit a procedural error by failing to chronicle exhaustively decisions it made in a factually distinguishable context.

One of the comments also faults the Agency for failing to give notice of the "several" citizen petitions filed since 1977 that request that the Agency regulate cigarettes. In fact, the Agency incorporated by reference into the docket for this jurisdictional determination all significant dockets opened since the conclusion of the *ASH* litigation that relate to the Agency's jurisdiction over cigarettes and other nicotine delivery systems. The index the Agency provided to the public on September 29, 1995, in conjunction with the public display of the administrative record (as of that date), included a description of 9 dockets the Agency incorporated by reference into the record supporting the Jurisdictional Analysis. *See* AR (Vol. 504 Ref. 8934).

regulatory authority over combination products, and the applicability of the medical device provisions of the Act to cigarettes and smokeless tobacco. Instead, one of these comments asserted that all the Agency had done was publish "a tendentious anti-tobacco, pro-FDA-regulation manifesto" and, as such, the Agency's notice was "fraudulent."[1249] The Agency disagrees with this characterization, whether it was directed at the Proposed Rule or at the Jurisdictional Analysis. More to the point, the Agency disagrees with the argument that the Agency somehow deprived the public of fair notice of its Jurisdictional Analysis.

Again, to satisfy the APA's notice requirement for informal rulemaking, the Agency must specify with particularity the legal authority on which its proposal is based. K. Davis, *Administrative Law Treatise* (3d ed. 1994), at 299. Notice must be "informative" and must "fairly apprise" interested persons. *Id.* at 299-300. The Agency notes, however, that it need not unravel for the public each and every theoretical step in the analysis. *See Chemical Waste Management, Inc. v. Environmental Protection Agency*, 869 F.2d 1526, 1535 (D.C. Cir. 1989) (even where Agency statement in notice of rulemaking assumes rather than invites comments on an issue, notice is sufficient if it provides interested parties "with a clear indication of the agency's intended course of action. . . . "); *Center for Auto Safety v. Peck*, 751 F.2d 1336, 1361 (D.C. Cir. 1985) ("It is simply not the case, however, that all of the essential postulates for an agency rule must be contained in the record").

[1249] Joint Comment of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 33. *See* AR (Vol. 526 Ref. 95).

VI.B.1.

Nevertheless, the Agency provided the public a detailed explanation of why it regards cigarettes and smokeless tobacco as drug/device combinations products, and why it believes the device provisions of the Act may, and should, be used to regulate these products. The Agency set forth its rationale for regulating these products as devices in both the Jurisdictional Analysis itself, *see* 60 FR 41521–41525, and in the Proposed Rule, *see* 60 FR 41348–41350. Further, the Agency identified for the public in the Proposed Rule the precise statutory provisions under which it proposed to regulate these products. 60 FR 41346–41352, 41372.

The Agency also put the public on notice, by referencing the Intercenter Agreement, *see* 60 FR 41521, that preloaded drug delivery systems are often regulated using the drug authorities under the Act. The Agency adequately explained—for notice purposes—why in this instance it proposed a different approach. 60 FR 41348–41350.

With respect to the application of the concept of "intended use," the lengthy discussion in Part II of the Jurisdictional Analysis provided the public with full disclosure of the Agency's rationale for regulating cigarettes and smokeless tobacco based on the "intended use" of these products. The core facts and precedents on which the Agency relied were displayed in a manner the Agency believes invited maximum public scrutiny. The Agency even provided the public with 11 different examples (9 from the 1980's and 1990's) of the application of the intended use concept to the determination of whether a product, absent express claims, may be regulated as a drug or a device. 60 FR 41527–41531. This level of explanation more than satisfied the requirements of the APA as interpreted by the relevant case law.

Finally, the quantity and quality of comments the Agency received on the Jurisdictional Analysis and the proposed rule suggest that, in fact, the public was adequately notified of the relevant issues. The Agency received more comments on these two documents than it has ever received on any other subject, with over 700,000 comments (including form letters) and over 95,000 distinct or unique sets of comments. More important, the Agency received hundreds of pages of comments on the very issues the Agency is said to have hidden from the public. Indeed, the two industry commenters who complained most vigorously about the supposed deficiencies in the Jurisdictional Analysis and the Proposed Rule themselves literally filed volumes of comments on the issues they claim the Agency concealed.[1250] Even the comments of interested nonindustry persons evidenced fair notice of the Agency's historical position and fair notice of the Agency's reasoning for applying the device provisions of the act to cigarettes and smokeless tobacco.[1251]

In *Chemical Waste Management*, 869 F.2d at 1535, the plaintiff complained that the Environmental Protection Agency's notice of proposed rulemaking treated a certain controversial issue "as an accomplished fact." Like two of the comments here, the plaintiff in *Chemical Waste Management* argued that the APA required the agency to

---

[1250] *See, e.g.*, Joint Comments of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 43-73 (discussing the Agency's historical position on Agency jurisdiction over tobacco products), 99-258 (discussing the Agency's application of the concept of intended use to tobacco products), and 259-307 (analyzing the Agency's position that cigarettes and smokeless tobacco are combination products that may be regulated as restricted devices). *See* AR (Vol. 526 Ref. 95). *Accord* Joint Comments of Cigarette Manufacturers at, among other places, Vol. I (discussing FDA's historical position on jurisdiction), Vol. II (discussing the concept of intended use), and Vol. V (discussing the regulation of cigarettes as medical devices). *See* AR (Vol. 535 Ref. 96).

[1251] *See, e.g.*, Public Citizen Litigation Group, Comment (Jan. 2, 1996), at 29-43. *See* AR (Vol. 700 Ref. 591); American Heart Association, Comment (Dec. 26, 1995). *See* AR (Vol. 700 Ref. 592).

highlight the fact that its position was subject to debate and to solicit comments on the issue. The United States Court of Appeals for the District of Columbia rejected this argument because EPA had provided notice of its intended course *and* because the agency in fact received numerous comments on the issue. *Id.*; *see also Shell Oil Co. v. EPA*, 950 F.2d 741, 757 (D.C. Cir. 1991) (recognition of a certain issue by commenters may be used to infer that adequate notice of the issue was given); *Haralson v. Federal Home Loan Bank Board*, 678 F. Supp. 925, 926 (D.D.C. 1987) (same).

As in cases such as *Chemical Waste Management*, the comments FDA received demonstrate that there is no serious claim to be made that the Agency has concealed issues from the public. Interested persons representing both sides in this controversial proceeding commented on the very issues the Agency supposedly underplayed in its notice of proposed rulemaking.

At bottom, the comments that challenge the adequacy of the Agency's proposal confuse the merits of the issue with procedure. The supposed deficiencies in FDA's legal reasoning, and the supposed failure to discuss contrary authorities, raise substantive issues to be resolved during the comment and response-to-comment phase of the proceeding. The possibility that some of the Agency's legal conclusions may be subject to debate does not render the notice inadequate. *See Chemical Waste Management,* 869 F.2d at 1535; *Natural Resources Defense Council, Inc. v. Hodel,* 618 F. Supp. 848, 864-865 (E.D. Cal. 1985).

2. The Agency Provided a "Reasoned Explanation" for Its Current Position

Several tobacco industry comments also claimed that the Agency violated the APA's notice provisions by failing to include a "reasoned explanation" for departing from past precedent on the issue of whether to regulate all cigarettes and smokeless tobacco. In their view, the Jurisdictional Analysis and Proposed Rule are procedurally infirm because the Agency did not adequately explain its basis for past decisions not to regulate these products, and did not distinguish those decisions from its present position. One of these comments likewise asserted that the Agency was required to include in the administrative record each and every document "that formed the basis for, or was an expression or reflection of, FDA's consistent position over more than 80 years that it does *not* have jurisdiction to regulate cigarettes." The absence of this material, according to the comment, demonstrates that the Agency failed to consider "obviously relevant" contrary information in asserting jurisdiction and in proposing to regulate these products.[1252]

The authorities cited in the comments require that, by the *close* of an administrative proceeding, the Agency must provide a "reasoned explanation" to the extent the Agency has departed from a prior formal position. *See, e.g., International Union, United Auto Workers v. NLRB*, 459 F.2d 1329 (D.C. Cir. 1972) (challenge to final decision of labor board); *Greyhound Corp. v. ICC,* 551 F.2d 414 (D.C. Cir. 1977) (challenge to final order of the ICC); *Baltimore and Annapolis Railroad Co. v. Washington Metro. Area,* 642 F.2d 1365 (D.C. Cir. 1980) (challenge to final order of

[1252] Joint Comments of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. XII, at 16. *See* AR (Vol. 535 Ref. 96).

transit commission); *RKO Gen., Inc. v. FCC*, 670 F.2d 215 (D.C. Cir. 1981), *cert. denied*, 456 U.S. 927 (1982) (challenge to final order of Federal Communications Commission denying renewal of television license); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto Insurance*, 463 U.S. 29, 43 (1983) (challenge to final rule rescinding passive restraint seatbelt requirement contained in a Department of Transportation standard). None of these cases, which involve challenges to final Agency orders and final rules, holds that at the notice stage of a proceeding, when an Agency is proposing to depart from a prior position, the Agency must provide a comprehensive "reasoned explanation."

The Agency nevertheless agrees that the rulemaking proceeding, taken as a whole, should clearly and rationally justify changes in existing policies. Thus, FDA included in its Jurisdictional Analysis ample reference to its prior policy and a more than ample discussion of the Agency's rationale for changing its policy. Indeed, the very intent of the Jurisdictional Analysis, the 622 footnotes supporting the analysis, its appendices, and the more than 13,000 documents put on the administrative record was to provide the public with a full view of the new evidence that supports the need for the Agency to take a different approach to the regulation of these products.

As FDA made clear at the outset of its Jurisdictional Analysis, its decision to propose to regulate these products, when in the past it did so only when claims were made, is based on the fact that "[t]he quality, quantity, and scope of the evidence available to FDA today is greater than any other time when FDA has considered regulation of cigarettes and smokeless products." 60 FR 41464, n.1. Footnote 5 of the Jurisdictional Analysis, in particular, made clear that: (1) The Agency in the past had declined to exercise jurisdiction generally over these products; and (2) the reason for taking a different

position today is that the evidence before the Agency regarding the intended use of these products "has changed dramatically." 60 FR 41482, n.5. In addition, the Agency repeatedly stated that its analysis was based on "evidence now available to the Agency," 60 FR 41464, "current evidence," 60 FR 41466, evidence accumulated since 1980, 60 FR 41482, n.5, and evidence that has emerged since 1980 or was not widely known until recently, 60 FR 41483–41484, 41539.

Neither the APA nor the case law cited in the comments requires an agency to provide a thorough "reasoned explanation" for departing from precedent at the notice stage of a proceeding. Rather, the APA at most requires that the Agency give notice of its proposal to take a different position or view, and give enough information to allow the public a reasonable opportunity to comment. Not until the close of the proceeding, after public comment has been received, must the Agency ensure that it has provided a full "reasoned explanation." The Agency believes in this instance that its discussion at the notice stage met the standard that courts ordinarily do not impose until the close of an administrative proceeding. Nonetheless, the Agency has provided further, detailed discussion of the legal and factual bases for taking its current position in this document. *See* section IV., above.

Finally, the Agency does not agree that it was required to include in the record, at the notice stage, each and every prior Agency "decision, statement, and finding." Rather, the Agency appropriately included in the record of proposed rulemaking enough documentation to give the public notice of the Agency's prior position, and notice of the Agency's prior reasoning for declining to exercise jurisdiction generally over these products (absent express claims). For example, the Agency incorporated by reference into

the administrative record for this jurisdictional determination all significant dockets opened since the conclusion of the 1977 *ASH* litigation that relate to the Agency's jurisdiction over these products. In addition, the Agency included in the record its response and supplemental response to the original *ASH* citizen petition. Those documents outline in detail the "contrary" view the Agency has allegedly concealed, including full discussions of the Agency's enforcement history with respect to tobacco products and the Agency's significant past pronouncements on the subject. In any case, the tobacco industry itself, through its comments, has introduced many of the Agency's earlier statements into the administrative record for this proceeding. Thus, unlike the facts presented in cases such as *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) and *Walter O. Boswell Memorial Hospital v. Heckler*, 749 F.2d 788 (D.C. Cir. 1984), as referenced in the comment, the administrative record for this proceeding already contains the "adverse" information claimed to be lacking, by virtue of the Agency's inclusion of documents in the record and the comments received by the Agency.

C. ADEQUACY OF THE COMMENT PERIOD

FDA received at least one comment urging that the comment period for both the Jurisdictional Analysis and the Proposed Rule was unreasonably short in light of the complexity of the Proposed Rule, the number of materials the Agency put on public display, and the possible impact of the rule on the tobacco industry. This comment argued that the Agency acted arbitrarily and capriciously in deciding to "limit" the comment period to 144 days from the publication of the August 11, 1995, Proposed Rule and Jurisdictional Analysis and 95 days from the public release of the documents FDA considered but did not rely upon.

VI.C.

Far from having "limited" the comment period, FDA provided more than twice as much time for comment as the Agency's regulations require. *See* 60 FR 53560 (Oct. 16, 1995) (extending comment period for Proposed Rule); 60 FR 53620 (Oct. 16, 1995) (extending comment period on Jurisdictional Analysis).

The APA requires only that an agency "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments. . ." 5 U.S.C. 553(c). This is all the APA requires; there is no statutory requirement concerning how many days an Agency must allow, nor is there a requirement that an Agency must extend the period at the request of an interested person. *See Phillips Petroleum Co. v. Environmental Protection Agency,* 803 F.2d 545, 559 (10th Cir. 1986).

FDA's own regulations generally afford the public 60 days to comment on a Proposed Rule, unless the Commissioner shortens or lengthens the period for good cause. 21 CFR 10.40(b)(2). Executive Order 12889 implementing the North American Free Trade Agreement prescribes a minimum comment period of 75 days on certain proposed rules, except when good cause is shown for a shorter comment period. *See* 58 FR 69681 (Dec. 27, 1993).

Here, the Agency provided the public with 144 days from the publication of the Jurisdictional Analysis, 139 days from the release of the documents the Agency cited in support of the Jurisdictional Analysis (on August 16, 1995), and 95 days from the release of the materials the Agency considered but did not directly rely upon (on September 29, 1995). Thus, even when counting from the date the Agency released additional documents on which it did not rely, the Agency provided much more time for comment than its regulations, or the Executive Order, require.